

Applicant : Helena Seppanen et al.  
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Attorney's Docket No.: 09910-007001 / BP100140/EH/TUK

REMARKS

Claims 1-26 are now pending. Claims 1-14 have been amended. Claims 15-26 have been added.

Submitted herewith at the request of the Examiner is a new submission of the entire specification, with claims. We understand that the copy of the application in the file has holes punched through the first line of text on every page. This new submission is a copy of the original application, as filed, from our files.

Claim 5 was rejected under U.S.C. §112, first paragraph. The rejection indicated that: “..the specification, while being enabling for using a protein as a surface tension releasing agent, does not reasonably provide enablement for all the proteins.” (Office Action, page 4).

Applicants submit that the specification is enabling for the use of proteins as STRAs, as claimed.

As explained by the Board of Appeals in Ex parte Forman, 230 U.S.P.Q. 546, 547 (1986), 35 U.S.C. §112, paragraph 1 requires applicants to provide a sufficient disclosure:

to enable one having ordinary skill in the relevant field to practice the invention claimed therein without the exercise of undue experimentation.

The Board went on to explain the factors that are considered in deciding when experimentation becomes “undue” (id.):

“The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art: Ansul Co. v. Uniroyal, Inc. [169 U.S.P.Q. 759, 762 (2d Cir. 1971)]. The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability of the art and the breadth of the claims. In re Rainer, 52 CCPA 1593, 347 F.2d 574, 146 USPQ 218 (1965); In re Colianni, *supra*.”

Applicants submit that a person skilled in the art reading the specification would be able to practice the invention of claim 5 without undue experimentation. The nature of the invention of claim 5 is the use of a protein surface tension releasing agent in the method of claim 1, in

which magnetic particles are adhered to a magnetic probe and the probe and particles are transferred to another medium. The specification provides a procedure to measure collection and release efficiency using a magnetic probe (e.g., page 8). Further, the specification illustrates an analysis of efficiency of collection and release data as a function of the concentration of STRAs (See Fig. 1 and text). Thus, a person of ordinary skill in the art can determine if a given protein improves particle collection efficiency, i.e., would be a suitable STRA, by following the procedures outlined in the specification. Applicants request that the rejection under §112, first paragraph be withdrawn.

The pending independent claims are claims 1, 13, and 14.

Claim 1 is directed to a process for the purification of a substance. A material containing the substance, and magnetic particles coated or treated with a reagent which binds the particles to the substance, are dispensed in a first medium. A binding reaction is let to take place, in which reaction the substance is bound to the particles. A magnetic probe is pushed into the medium, whereby particles adhere to the probe. The probe together with the particles and the substance bound to them is transferred to a second medium. A surface tension releasing agent is dispensed in at least one of the mediums.

Claim 13 is directed to a method for separating magnetic particles by a magnetic probe from a medium. The method consists of the step of dispensing a surface tension releasing agent into the medium before the particles are separated from the medium.

Claim 14 is directed to a method for improving the adherence of magnetic particles from a liquid medium to a magnetic probe to be pushed into the medium. The method consists of the step of dispensing a surface tension releasing agent into the medium before the particles are adhered to the probe.

As described in the specification, embodiments of the invention provide high yields of purified substance using STRAs to facilitate a complete collection and transfer of particles from one medium to the next. When a magnetic probe is inserted into the medium containing the particles and STRAs, the particles adhere well to the probe and a complete collection of particles is accomplished. In the absence of STRAs, the relatively high viscosity of the medium and the relatively small size of the magnetic particles, e.g., 0.5 to 10  $\mu\text{m}$ , may cause the particles to not

adhere to the magnetic probe. This lack of adherence of particles to the probe will lower the efficiency of collection and transfer of particles during every step.

An advantage of embodiments is that, by using a probe to transfer particles, and by including STRAs in the medium, the yield of the purified substance is higher. STRAs increase collection efficiency in the following manner. First, STRAs prevent the particles from adhering to the walls of the reaction vessel, thereby increasing the probability of the particles adhering to the probe. Second, since the particles don't adhere to the walls of the reaction vessel, they form a uniform suspension in the medium, and the diffusion distances of the particles to the probe are short, thereby increasing collection efficiency. Third, STRAs facilitate loosening and release of particles from the surface of the probe into the medium into which the particles are being transferred when the magnetic force is removed.

Independent claims 1, 13, and 14 have been rejected under §35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5, 705, 628 (Hawkins) or U.S. Patent No. 4,454,234 (Czerlinski) in view of U.S. Patent No. 6,448,092 (Tuunanen). Applicants traverse.

Hawkins does not disclose or suggest using a magnetic probe. Rather, Hawkins describes a method in which a magnet external to the reaction vessel aggregates magnetic particles in the reaction vessel; the particles adhere to the wall of the reaction vessel and the supernatant is removed (see for e.g., col. 6 line 3-8). The magnetic particles bearing the substance are thus separated from the medium. Thus, in the method described by Hawkins, it is desirable for the particles to adhere to the wall of the reaction vessel. Hawkins could not suggest the use of STRAs in combination with a magnetic probe, as Applicants claim. As indicated above, an advantage of embodiments of applicants' methods is that STRAs prevent particles from adhering to the wall of the reaction vessel. *not recited in the claims*

Likewise, Czerlinski describes a method of separating magnetic particles coated with the substance to be purified with an external magnetic field (see, for e.g., col. 8, line 56-58; col. 9, line 38-39). Czerlinski also discloses particle separation by sedimentation followed by siphoning off of the supernatant (see for e.g., the procedure described in Example 5). Thus, as discussed above for Hawkins, the use of STRAs in combination with a magnetic probe could not have been disclosed or suggested by Czerlinski.

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Tuunanen discloses the use of a magnetic probe to collect magnetic particles and transfer them to another medium. But, Tuunanen does not disclose or suggest inclusion of STRAs in a medium.

Clearly, there is no motivation to combine the teachings of Hawkins or Czerlinski and Tuunanen since a completely different approach is used by Hawkins or Czerlinski relative to Tuunanen for separating magnetic particles from the medium. Accordingly, applicants request that the rejection under 103(a) be withdrawn.

Claims 2-12 depend from independent claim 1 and are patentable over the cited references for at least the same reasons.